Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (currently amended) A method for determining the presence of an acute ~~the detection of a~~ renal tubular cell injury in a mammal, including an ischemic renal injury and a nephrotoxic injury, comprising the steps of:

(a) providing ~~obtaining a~~ urine sample from a mammalian subject that is suspected of having ~~or being prone to develop a~~ an acute renal tubular cell injury;

(b) contacting the urine sample with an antibody for neutrophil gelatinase-associated lipocalin (NGAL), to allow formation of a complex of the antibody and the NGAL; [[and]]

(c) detecting the antibody-NGAL complex; and

(d) correlating the detected antibody-NGAL complex to the presence of the acute renal tubular cell injury.

2. (previously presented) The method according to Claim 30 wherein the urine sample comprises a plurality of urine samples from the subject that are obtained intermittently or continuously.

3. (previously presented) The method according to Claim 2 wherein the plurality of urine samples are obtained continuously.

4. (previously presented) The method according to Claim 31 wherein the step of detecting the antibody-NGAL complex comprises contacting the complex with a second antibody for detecting the NGAL.

5. (previously presented) The method according to Claim 30 wherein the mammalian subject is a human.

6. - 8. (canceled)

9. (previously presented) The method according to Claim 31 wherein the antibody is a capture antibody for the NGAL.

10. (previously presented) The method according to Claim 9 wherein the step of detecting the antibody-NGAL complex comprises the steps of:

(1) separating any unbound material of the urine sample from the capture antibody-NGAL complex;

(2) contacting the capture antibody-NGAL complex with a second antibody for detecting the NGAL, to allow formation of a second complex between the second antibody and the capture antibody-NGAL complex;

(3) separating any unbound second antibody from the second antibody complex; and

(4) detecting the second antibody of the second antibody complex.

11. (currently amended) The method according to Claim 10 wherein the step [[i)]] (i) comprises the step of contacting the urine sample with a media having affixed thereto the capture antibody.

12. – 27. (canceled)

28. (currently amended) A method for determining the presence of an acute ~~the detection of a~~ renal tubular cell injury, including an ischemic renal injury and a nephrotoxic injury, in a mammalian subject, comprising the steps of:

(a) contacting a urine sample comprising up to 1 milliliter of the first urine obtained from a mammalian subject within 24 hours of ~~an event that causes~~ an acute renal tubular cell injury to the mammalian subject caused by an event, with an antibody for neutrophil

gelatinase-associated lipocalin (NGAL), to allow formation of a complex of the antibody and NGAL;

(b) detecting the antibody-NGAL complex; and

(c) correlating ~~evaluating the renal tubular cell injury status of the subject based on~~ the level of the detected antibody-NGAL complex with the presence of the acute renal tubular cell injury ~~present in the urine sample~~.

29. (canceled)

30. (currently amended) A method for ~~evaluating the~~ determining the presence of an acute renal tubular cell injury in ~~status of~~ a mammalian subject, wherein the method comprises the steps of:

(a) detecting the presence of any neutrophil gelatinase-associated lipocalin (NGAL) in a urine sample obtained from a mammalian subject that is suspected of having ~~or being prone to develop a~~ an acute renal tubular cell injury; and

(b) correlating the presence ~~evaluating the renal tubular cell injury status of the subject based on the level~~ of NGAL ~~present~~ in the urine sample to the presence of the acute renal tubular cell injury.

31. (previously presented) The method according to claim 30, wherein the detecting of NGAL is done by

(i) contacting the urine sample with an antibody for NGAL to allow formation of a complex of the antibody with any NGAL present in the urine sample; and

(ii) detecting the antibody-NGAL complex as a measure of the level of the NGAL.

32. (currently amended) The method according to claim 30, wherein the acute renal tubular cell injury is ~~comprises an injury~~ selected from the group consisting of an acute ischemic

renal injury [[, a]] and an acute nephrotoxic injury~~, and another injury that affects the tubular cells of the kidney~~.

33. (currently amended) The method according to claim 30, wherein the method is used to detect NGAL present in a sample of the first urine output of the subject immediately ~~after the onset of~~ following the acute renal tubular cell injury.

34. (currently amended) The method according to claim 30, wherein the urine sample is obtained within 24 hours after an event that causes the mammalian subject to have~~, or to be prone to developing,~~ the acute renal tubular cell injury.

35. (currently amended) The method according to claim 30 wherein the urine sample is obtained within a period of time following the acute renal tubular cell injury ~~the event~~, the period of time selected from the group consisting of 6 hours, 4 hours, 3 hours, 2 hours, 1 hour, and 30 minutes.

36. (currently amended) The method according to claim 35 wherein the acute renal tubular cell injury is caused by an event ~~makes the mammalian subject develop or be prone to develop acute renal failure~~.

37. (currently amended) The method according to claim 36 wherein the event is selected from the group consisting of: (a) a surgical procedure selected from the group consisting of cardiac surgery, coronary bypass surgery, ~~cardiovascular surgery,~~ and vascular surgery; (b) kidney transplantation; (c) administration of a nephrotoxic agent; ~~and~~ (d) a cardiovascular event; and (e) ~~the onset of~~ a condition selected from the group consisting of stroke, trauma, sepsis, and dehydration.

38. (currently amended) The method according to claim 36 wherein ~~the event is one that causes the admission of~~ the mammalian subject is a patient in [[to]] an intensive care unit.

39. (currently amended) The method according to claim 31 wherein the method is used to ~~predict,~~ diagnose[[,]] or monitor ~~or determine the likelihood of a~~ the acute renal tubular cell injury.

40. (currently amended) The method according to claim 31 wherein the NGAL level is contrasted with a urinary NGAL value that distinguishes a mammalian subject that has [[a]] an acute renal tubular cell injury, from a mammalian subject that does not have an acute renal tubular cell injury.

41. – 45. (canceled)

46. (currently amended) A method for determining the presence of an acute ~~the detection of a~~ renal tubular cell injury in a mammal, including an ischemic renal injury and a nephrotoxic injury, comprising the steps of:

(a) contacting a urine sample from a mammalian subject that is suspected of having ~~or being prone to develop a~~ an acute renal tubular cell injury, with an antibody for neutrophil gelatinase-associated lipocalin (NGAL), to allow formation of a complex of the antibody and the NGAL; [[and]]

(b) detecting the antibody-NGAL complex; and

(c) correlating the detected antibody-NGAL complex to the presence of the acute renal tubular cell injury.

47. (New) The method according to claim 46, wherein the step of detecting the antibody-NGAL complex further comprises determining the level of antibody-NGAL complex, and wherein the level of antibody-NGAL complex correlates with the extent of the acute renal tubular cell injury.

48. (New) The method according to claim 1 wherein the step of detecting the antibody-NGAL complex further comprises determining the level of the antibody-NGAL complex, and wherein the step of correlating comprises correlating the level of the antibody-NGAL complex to the extent of the acute renal tubular cell injury.

49. (New) The method according to claim 1 wherein the mammalian subject is prone to develop acute renal failure secondary to the acute renal tubular cell injury.

50. (New) The method according to claim 30, wherein the acute renal tubular cell injury is an acute ischemic renal tubular cell injury.

51. (New) The method according to claim 30, wherein the acute renal tubular cell injury is an acute nephrotoxic injury.

52. (New) The method according to claim 30, wherein the urine sample is an unprocessed urine sample.

53. (New) The method according to claim 30 wherein the mammalian subject is prone to develop acute renal failure secondary to the acute renal tubular cell injury.

54. (New) The method according to claim 31 wherein the method is used to predict acute renal failure secondary to the acute renal tubular cell injury.

55. (New) The method according to claim 31 wherein the level of NGAL correlates with the extent of the acute renal tubular cell injury.

56. (New) The method according to claim 46 wherein the mammalian subject is prone to develop acute renal failure secondary to the acute renal tubular cell injury.

57. (New) A method for detecting the development of acute renal failure secondary to an acute renal tubular cell injury in a mammal, including an ischemic renal injury and a nephrotoxic injury, comprising the steps of:

(a) providing a urine sample from a mammal that has an acute renal tubular cell injury;

(b) contacting the urine sample with an antibody for neutrophil gelatinase-associated lipocalin (NGAL), to allow formation of a complex of the antibody and the NGAL;

(c) detecting the antibody-NGAL complex; and

(d) correlating the detected antibody-NGAL complex to the development of acute renal failure secondary to the acute renal tubular cell injury.

58. (New) The method according to claim 57 wherein the step of detecting the antibody-NGAL complex further comprises determining the level of the antibody-NGAL complex, and wherein the step of correlating comprises correlating the level of the antibody-NGAL complex to predicting acute renal failure secondary to the acute renal tubular cell injury.

59. (New). A method for determining the presence of an acute renal tubular cell injury in a mammalian subject, wherein the method comprises the steps of:

(a) detecting the presence of any neutrophil gelatinase-associated lipocalin (NGAL) in a urine sample obtained from a mammalian subject that is suspected of having an acute renal tubular cell injury caused by an event, the event selected from the group consisting of: (i) a surgical procedure selected from the group consisting of cardiac surgery, coronary bypass surgery, and vascular surgery; (ii) kidney transplantation; and (iii) administration of a nephrotoxic agent; and

(b) correlating the presence of NGAL in the urine sample to the presence of the acute renal tubular cell injury.